

**AUG 24 2001**

**510(K) SUMMARY  
(as required by 807.92(c))  
K003924**

**Submitter of 510(k):** Mavidon Medical Products  
2105 7<sup>th</sup> Ave. N.  
Lake Worth, FL 33461

**Phone:** 1-800-654-0385

**Contact Person:** Tim Carroll

**Date of Summary:** December 2, 2000

**Trade Name:** Mavidon Medical Electrode Jelly

**Classification Name:** Electrode Gel

**Predicate Device:** Chester Labs, Statsign Electrode Conductivity Gel, K001705

**Device Description/  
Comparison:** A thixotropic conductive gel for use with silver, gold or tin electrodes. The device is the same as the predicate device except for a slight color variation.

**Intended Use:**

The Mavidon Medical Electrode Jelly is recommended for use with silver, gold or tin electrodes in EEG, ECG, EMG, TENS and Muscle Stimulation procedures.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 24 2001

Mr. Timothy J. Carroll  
President  
Mavidon Medical Products  
2105 7<sup>th</sup> Avenue North  
Lake Worth, Florida 33461

Re: K003924  
Trade/Device Name: Mavidon Medical Electrode Jelly  
Regulation Number: 882.1275  
Regulatory Class: II  
Product Code: GYB  
Dated: May 19, 2001  
Received: June 4, 2001

Dear Mr. Carroll:

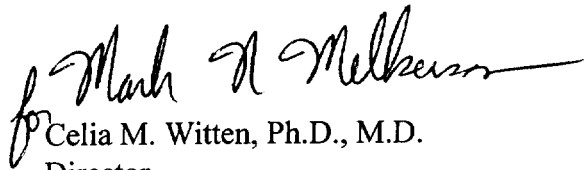
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a long horizontal flourish extending to the right.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K003924

Device Name: Mavidon Medical Electrode Jelly

**Indications For Use:**

The Mavidon Medical Electrode Jelly is recommended for use with silver, gold or tin electrodes in EEG, ECG EMG, TENS and Muscle Stimulation procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

*for Mark N. Melhus*  
(Division Sign-Off)

Division of General, Restorative  
and Neurological Devices

510(k) Number K 003924